K132170

510(K) Summary

Submitter:	Shaser, Inc. 10 Maguire Road Lexington, MA 02421 781-995-2246
Contact:	Anthony Burns, Senior Director of Regulatory Affairs
Summary Prepared:	July 12, 2013
Device Trade Name:	Shaser V-MINI RX
Common Name:	Light Based Hair Removal Device
Classification Name:	Product Code ONF: Powered Light Based Non-Laser Surgical Instrument with Thermal Effect
Equivalent Device:	Shaser V-MINI (K130015), Radiancy SpaTouch (K020856), Radiance SkinStation (K051671)
Device Description:	Shaser V-MINI RX is an IPL device with a wavelength range of 400-1200 nm. The proposed device removes hair by way of Selective Photothermolysis; the preferential thermal treatment of target tissue without collateral effect of surrounding tissue. The pulsed light heats the hair bulb which disables hair growth. The proposed device is intended for males and females to remove unwanted hair from body sites (legs, arms, chest, underarms, stomach, and bikini line) and from facial sites (chin, cheek, chin, neck, side burns, and above the lips). The V-MINI RX is a battery powered, portable device. Electrical requirement (battery charger) is 115 VAC, 15A, 50-60 Hz, single phase.
Intended Use:	The Shaser V-MINI RX Hair Removal System is intended to provide phototherapeutic light to the body and is generally indicated to treat dermatological conditions. It is also intended for removal of unwanted hair by using a selective photothermal treatment. The Shaser V-MINI RX Hair Removal System is indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician, after training by a healthcare professional. It is also indicated for the removal of unwanted body and/or facial hair in adults with Fitzpatrick skin types I – VI. The Shaser V-MINI RX Hair Removal System is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

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Technical Characteristics:	The Shaser V-MINI RX is the exact same device as the V-MINI predicate device; with the same technical characteristics – same design (with the exception of a larger spot size, higher maximum energy level, and wider wavelength range), the same components and materials, powered by the same energy source. None of these differences raises new issues of safety and efficacy.
Comparison:	The Shaser V-MINI RX has the same intended use, the same principle of operation and method of action, similar pulse energy range, and very similar wavelength range as the SkinStation and V-MINI predicate devices.
Nonclinical Performance Data:	None.
Clinical Performance Data:	None
Conclusion:	The V-MINI RX is a safe and effective device for the intended use.
Additional Information:	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Shaser, Incorporated
Mr. Anthony Burns
Senior Director of Regulatory Affairs
10 Maguire Road
Lexington, Massachusetts 02421

November 26, 2013

Re: K132170
Trade/Device Name: Shaser V-MINI RX
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: September 18, 2013
Received: September 19, 2013

Dear Mr. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132170

Device Name: Shaser V-MINI RX

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Prescription Use ____√____ OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

(Division Sign-Off) for BSA

Division of Surgical Devices

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